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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/014,705 | 12/11/2001 | Scott J. Addonizio | 1133279-0014 | 7327 |

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT PAPER NUMBER

3738

DATE MAILED: 03/12/2004

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/014,705

Applicant(s)

ADDONIZIO ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 28 and 34-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27, 29, 30, 32 and 33 is/are rejected.
- 7) ☒ Claim(s) 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 December 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, Species 1, claims 1-27 and 29-37 in Paper No. 6 is acknowledged. The traversal of the group restriction is on the ground(s) that "the stent according to the instant invention cannot be made from a continuous piece of wire as the Examiner asserts". This is not found persuasive because the examiner did not assert that the wire has to be continuous. The stent can be made from distinct elements that are joined together, as stated on page 4, lines 16-17 of the specification, wherein the elements are wire pieces. The traversal of the species requirement is on the ground(s) that the two embodiments alleged by the Examiner to be patentably distinct are, in effect, under a single genus of patentable subject matter, and all of the presently elected claims read on the elected embodiment, i.e. a stent with end zones. This is not found persuasive because the presence of end zones is not the only structural difference between the embodiments of Species 1 and 2. Figures 12-15 of Species 2 clearly shows first circumferential elements 50' of the stent being substantially identical to the second circumferential element 60 except that they are rotated to have a different orientation. See page 8, lines 29-31. This different orientation is another structural difference that deems the two embodiments of the patentably distinct. The requirement is still deemed proper and is therefore made FINAL.

2. Claims 28 and 38-42 have been withdrawn for being drawn to the non-elected invention of Group II. Additionally, claims 34-37 have been withdrawn for being drawn to the non-elected

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Species 2. The claims being considered for further examination on the merits are 1-27 and 29-33.

Response to Amendment

3. The amendment filed on 12/18/03 has been entered as Paper No. 6. The changes to the specification and claims have been approved by the examiner.

Priority

4. Applicant is reminded that in order for a patent issuing on the instant application to obtain the benefit of priority based on priority papers filed in parent Application No. 09/511,481 under 35 U.S.C. 119(a)-(d) or (f), a claim for such foreign priority must be made in this application. In making such claim, applicant may simply identify the application containing the priority papers.

Drawings

5. The drawings are objected to because of the following:
- a) In Figure 1, it appears that the bottom "10" should be changed to --20-- for reference to the "second end zone".
 - b) It appear from page 4, line 35 and page 5, line 2 that 66' in Figure 3 should be changed to --66--.

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A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: reference number “310” in Figure 4 is not mentioned in the specification. The examiner suggests mentioning it on page 6, line 3 after “period”, such as --period 310--. Reference number “K” in Figures 14 and 15 is also not mentioned in the specification. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

7. The abstract of the disclosure is objected to because on lines 2-3, the portion of the sentence that reads “and the comprises at least two a first and second set of helical segments” does not make sense. Correction is required. See MPEP § 608.01(b).

8. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

a) Claim 9 requires that the angle formed by the linear segments be greater than 0 degrees. This is not commensurate in scope (the claim limitation is broader) with what is

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disclosed in the specification, which at page 8, lines 11-12 discloses the angle as ranging from 0 to 45 degrees.

b) Claim 19 requires that at least one first helical segment cross at least one second helical segment. This is not commensurate in scope (the claim limitation is broader) with what is disclosed in the specification. There is no support for only one first helical segment crossing only one second helical segment when there are a plurality of first and second expandable helical segments.

c) Claim 25 requires that the linear segments of the first helical segments lie at an angle between 0-45 degrees. There is no support for this limitation in the specification; see for example Figure 5 and page 5, lines 16-19.

← describing Species 2? (pgs 12-15?)
if so, doesn't show different pitch,
a req. by claim 19.

Because the above claim limitations were originally filed, they should now be included into the written specification.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 5 recites the limitation "each endzone" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. It appears that claim 5 should be dependent on claim 4 rather than on claim 1.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-27, 29, 30, 32 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Cottone, Jr. et al. (USPAP 2002/0116044).

13. The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C.

102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Cottone, Jr. et al. discloses an expandable stent will all the elements of claims 1, 10, 19 and 29. See Figure 4 for a plurality of expandable helical segments (39, 40) and Figure 1 for a plurality of main body cylindrical elements (1-34) being attached to one another by the helical segments (39, 40). See Figure 4 for second expandable circumferential segments (46-48) having a circumferential dimension that is less than the first expandable segment (1-33) circumferential dimension, and connecting together second expandable circumferential segments of adjacent cylindrical main body elements in helical patterns, thereby forming a plurality of generally parallel helices (39, 40) in the main body. See Figure 4 for a plurality of first expandable helical

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segments (1-33) having a different pitch value than the pitch of a plurality of second expandable helical segments (39, 40), and a first helical segment crossing at least one second helical segment. See Figure 4 for first expandable segments from adjacent cylindrical elements being connected with each other to form a plurality of first helical segments (1-33) having a pitch that differs from the pitch of a plurality of second helical segments (39, 40) formed by connecting second expandable segments from adjacent cylindrical elements with each other.

Claims 2, 3, 14, 17, 18, 20, 23-26, 30 and 33, see Figures 1 and 4 for stent structure.

Claims 4-10, 12, 15, 16, 21, 22 and 32, see Figure 7 and [0037] for structure of end zones (81), including connection elements (90-92).

Claims 11 and 27, see [0037] for the stent being radiopaque.

Claim 13, see [0030] for the stent being manufactured from a contiguous piece of material.

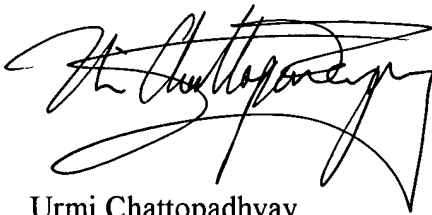
Allowable Subject Matter

14. Claim 31 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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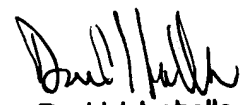
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.

A handwritten signature in black ink, appearing to read 'Urmi Chattopadhyay', with a stylized, flowing script.

Urmi Chattopadhyay

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A handwritten signature in black ink, appearing to read 'David J. Isabella', with a stylized, flowing script.
David J. Isabella
Primary Examiner